UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

EUGENE SHAPIRO, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. TG THERAPEUTICS, INC., MICHAEL S. WEISS, SEAN A. POWER, and ADAM WALDMAN Defendants.	No. 22-cv-06106 (JSR)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE AMENDED CLASS ACTION COMPLAINT

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[1] *See* Declaration of Adam M. Harris, dated November 17, 2022, filed herewith.

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PRELIMINARY STATEMENT

TG Therapeutics, Inc. ("TG" or the "Company") is a commercial stage biopharmaceutical company that develops and tests experimental drugs for the treatment of several serious and life-threatening diseases, including B-cell malignancies and autoimmune diseases. One such treatment is a combination therapy known as U2. U2 consists of two drugs: one known as "UKONIQ"—a TG drug that was approved by the United States Food & Drug Administration ("FDA") on the first day of the alleged Class Period (February 5, 2021 to May 31, 2022)—and another investigational antibody developed by TG, called ublituximab. Among other potential indications, TG studied U2 for chronic lymphocytic lymphoma ("CLL"), the most common form of adult leukemia in the United States, which currently has no cure and primarily impacts elderly patients. TG sponsored the "UNITY-CLL" Phase 3 clinical trial to study this potential use.

In September 2021, seven months after the start of the alleged Class Period, the FDA requested that TG analyze "Overall Survival" ("OS") data in the UNITY-CLL trial, which required an evaluation of the number of individuals who had participated in the trial and had subsequently died from any cause. OS was not included as a primary endpoint in the study protocols submitted to FDA. Per the FDA request, TG analyzed the OS data promptly. Thereafter, on November 30, 2021, the Company announced that the FDA had recently notified TG that the FDA planned to convene a meeting of the Oncologic Drugs Advisory Committee ("ODAC"), an advisory group, in connection with its review of U2 as a treatment for CLL, which appeared to be based on FDA's own assessment of the OS data. However, as publicly reported by TG in the November 2021 announcement (without challenge in the Amended Complaint), TG's assessment of this data following the September 2021 FDA request was that, once COVID-related deaths were excluded and missing data was obtained, there was no meaningful imbalance between deaths in the study's "treatment arm" (those receiving U2) and in the control group. Nevertheless, TG warned investors

that the FDA might disagree with the Company's assessment of the data, which could adversely affect the Company's prospects. Following this announcement, the Company's stock price fell.

Pleading classic "fraud by hindsight," Plaintiffs allege that because the more pessimistic scenario that was projected and disclosed did ultimately unfold through June 2022 (including the withdrawal of the supplemental new drug application ("sNDA") for U2 and the withdrawal of UKONIQ from the market after new data was analyzed in April 2022) there must have been "fraud." The Amended Complaint fails to state a claim and should be dismissed for several reasons.

First, Plaintiffs have failed to plead any false or misleading statement or actionable omission. Plaintiffs' entire theory of liability rests on the alleged existence of "SAEs"—serious adverse events (including deaths)—occurring during the Class Period. But they do not plead that the existence or reporting of SAEs rendered any statement by TG false or misleading. In any event, many of the alleged misstatements are non-actionable opinions or forward-looking statements that are accompanied by meaningful cautionary language. Indeed, the only affirmative statements by TG they seriously purport to challenge are statements of opinion in which TG executives stated their "belief" that TG's UKONIQ product was "differentiated" from competitors in terms of its safety profile. Plaintiffs plead no facts to suggest that these opinions are actionable—including because there are no allegations that any comparison embedded in these opinions was false (let alone knowingly false). In fact, Plaintiffs plead no facts about the relative safety of the competitor products, as to SAEs or anything else.

In recognition that Plaintiffs have not alleged any false or misleading statement, the Amended Complaint instead suggests that TG had a duty to disclose to investors the alleged SAEs as they occurred. That, too, fails. As the U.S. Supreme Court has held, SAEs in and of themselves are not material and do not need to be disclosed to investors absent "something more" than their

mere occurrence. But the Amended Complaint is devoid of *anything* more. The Amended Complaint's conclusion that SAEs were supposedly occurring "at an alarming frequency" does not suffice. Nor have Plaintiffs pled a claim premised on the fact that TG did not disclose the FDA's September 2021 information request prior to the Company's November 2021 announcement concerning the ODAC; it is well established that interim requests for information by the FDA are routine in the drug development process and do not by themselves give rise to any disclosure obligation.

Plaintiffs also fail to reconcile their theory that U2 was supposedly doomed based on the OS data with the initial reaction by the FDA to this data. As Plaintiffs acknowledge, the FDA was in the best position to assess the potential importance of the data. Yet, after analyzing the September 2021 OS data, the FDA scheduled an ODAC meeting for *over five months later*, in April 2022. It did not withdraw UKONIQ from the market, and it was not until late January 2022 that the FDA imposed a partial clinical hold on the UNITY-CLL trial, temporarily halting enrollment of new study subjects, *while still allowing treatment of enrolled subjects who were deriving benefit*. Those actions are not consistent with the supposedly "alarming" narrative Plaintiffs attempt to craft in the Amended Complaint.

Second, Plaintiffs have failed to plead an inference of scienter, let alone a strong one. There are no alleged insider sales. Rather, the only allegations of purported "motive" are that two of the three Individual Defendants had compensation tied to *FDA regulatory milestones* for TG's products. Even if this generic allegation could constitute a meaningful motive (it can't), there is no allegation that TG ever misled the FDA or improperly achieved any regulatory milestones. To the contrary, Plaintiffs' claims are largely premised on SAE reports that were contemporaneously made to the FDA.

Similarly, Plaintiffs do not allege any conscious misbehavior or recklessness by any Defendant. At bottom, their claims allege nothing more than fraud by hindsight based on a false narrative: that SAEs occurring before the FDA determined to convene an ODAC dramatically affected the drugs' safety profile and therefore significantly imperiled UKONIQ and approval of U2. But there are no facts alleged to support that narrative. Critically, Plaintiffs make no particularized allegations of fraud supported by any witness (confidential or otherwise), any TG internal documents, any FDA communications, or any other factual support. At most, the Amended Complaint suggests that one of the three Individual Defendants was aware of a "pocket" of SAEs at an unspecified time—but they do not allege that any SAE data actually contradicted the Defendants' public statements, or that Defendants had reason to believe that adverse action by the FDA was likely prior to November 2021, when TG announced the FDA's intention to convene an ODAC and warned that, notwithstanding the Company's own continued optimism, less favorable outcomes were possible. And even then, *the FDA did not place a clinical hold on the CLL trial, withdraw its approval of UKONIQ, or change UKONIQ's label*. The Amended Complaint does not come close to pleading facts suggesting that Defendants disbelieved their own statements. And while Plaintiffs continue the Class Period into 2022, when less favorable outcomes came to pass (after more recent data was analyzed and the Company and FDA took additional actions in response), there is no allegation from which to infer that any of the Individual Defendants knew of those events beforehand. In short, the Amended Complaint does not come close to pleading the requisite strong inference of scienter to state a securities claim.

Accordingly, the Amended Complaint should be dismissed with prejudice.

FACTUAL BACKGROUND[2]

TG Therapeutics. TG is a New York-based, commercial-stage biopharmaceutical company founded in 2011 that has developed and tested experimental drugs to treat several serious and deadly diseases, including deadly cancers non-Hodgkin Lymphoma ("NHL"), marginal zone lymphoma ("MZL"), follicular lymphoma ("FL"), and CLL, as well as multiple sclerosis and other autoimmune diseases. ¶¶ 2, 3, 68; 10-K (March 1, 2021) at 7-8.

The Individual Defendants. Defendant Michael S. Weiss has served as TG's Chairman, Chief Executive Officer, and President since the Company's founding in December 2011. 4/30/21 Proxy Statement at 6. Defendant Sean A. Power has served as TG's Chief Financial Officer since the Company's founding. *Id.* at 14. Defendant Adam Waldman joined TG in June 2018 as Chief Commercial Officer. 8/7/18 Press Release.

Umbralisib (UKONIQ). One of TG's drug products, Umbralisib, known by the commercial name UKONIQ, belongs to a class of drugs known as PI3K-delta inhibitors, an innovative treatment approach to certain cancers and autoimmune diseases that has been recognized in the market as "historically challenging" to commercialize. ¶¶ 3, 6, 74 (citing Cantor Fitzgerald Analyst Report published on November 6, 2019). Prior to the Class Period, TG received Breakthrough Therapy Designation for UKONIQ as a treatment for adult MZL patients.[3] 10-K (March 1, 2021) at 13. On February 5, 2021, the first day of the Class Period, TG announced that

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[2] This factual background is drawn principally from the Amended Complaint, which is presumed true for purposes of this motion only, and publicly available information referenced therein or on which it necessarily relies. References to "¶" refer to paragraphs of the Amended Complaint. Unless otherwise noted, emphasis is added and internal citations are omitted.

[3] "Breakthrough Therapy Designation" allows sponsors to expedite the development and review of a drug candidate upon a showing that the drug is intended to treat serious or life-threatening diseases and that preliminary clinical evidence "indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." 10-K (March 1, 2021) at 26.

it had received the FDA's accelerated approval for UKONIQ as a treatment for MZL and FL, which would allow for the drug's commercialization. ¶¶ 17, 104; 10-K (March 1, 2021) at 13.

U2. The treatment known as "U2" is a combination therapy of UKONIQ and another investigational drug developed by TG, ublituximab. ¶¶ 3, 68-69; 10-K (March 1, 2022) at 5, 9. Beginning in September 2015, TG proceeded under agreement with the FDA regarding its Phase 3 randomized controlled clinical trials for U2 to assess U2 as a combination therapy for CLL, which is the most common form of adult leukemia in the United States (the "UNITY-CLL" trial). 10-K (March 1, 2021) at 8, 13. This randomized controlled clinical trial, whose primary endpoint was progression free survival ("PFS"),[4] had 600 patients across four arms of treatment: (i) U2 combination therapy; (ii) ublituximab alone; (iii) umbralisib (UKONIQ) alone; (iv) and a control arm of competitor therapies obinutuzumab plus chlorambucil. ¶ 79; 10-K (March 1, 2021) at 5-6, 13. U2 was also assessed in Phase 2b trials (the "UNITY-NHL" trial) for MZL and FL, two subtypes of NHL, and diffuse large B-cell lymphoma. ¶¶ 8, 72; 10-K (March 1, 2021) at 5, 8, 13.

In October 2020, approximately four months prior to the beginning of the Class Period, TG received "Fast Track" designation for the U2 combination therapy as a treatment for CLL, leading to rolling submission of data from the UNITY-CLL trial in support of the therapy's Biologics License Application ("BLA") submission. 10-K (March 1, 2021) at 14.[5]

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[4] "Progression Free Survival" is defined as "the time from randomization [in a clinical trial] until objective tumor progression or death, whichever occurs first." FDA Industry Guidance (December 2018).

[5] "Fast Track" designation allows sponsors to submit portions of a New Drug Application ("NDA") or BLA to the FDA on a rolling basis upon a showing that the drug candidate is intended to treat a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs. 10-K (March 1, 2021) at 26. FDA approval of an NDA or BLA submission for a drug candidate allows for the drug's commercialization. FDA New Drug Application, https://www.fda.gov/drugs/types-applications/new-drug-application-nda; FDA, Biologics License Applications Process, https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber. A sponsor may also submit additional information and data in a supplemental NDA ("sNDA"). ¶ 7 n 2.

September 2021 FDA Request and November 2021 ODAC Announcement. As a general matter, a company like TG works together with the FDA "on the design and rollout of its clinical trials as well as data as well as data submissions," maximizing the flow of accurate information to the regulator with the scientific expertise to evaluate the safety and efficacy of a potentially life-extending or saving drug candidate. ¶¶ 7-9, 75-77, 82. In September 2021, the Company received a letter from the FDA requesting an analysis of OS data for the UNITY-CLL trial. ¶ 27. "OS" analysis requires an evaluation of "the time from randomization [in a clinical trial] until death *from any cause*."[6] As noted, the primary endpoint of the UNITY-CLL trial had been PFS, not OS. Accordingly, OS had not previously been analyzed.

Thereafter, on November 30, 2021, the Company announced that the FDA had notified the Company of its intention to hold an ODAC meeting to discuss issues that appeared to stem from an "early analysis of overall survival from the UNITY-CLL trial" that had been requested in September. ¶¶ 32, 123.[7] An ODAC provides the FDA with independent expert advice regarding drug products based on its review of data presented concerning safety and effectiveness.[8]

In its press release issued on November 30, 2021 announcing the FDA's intention to hold an ODAC meeting, TG reiterated the risks that safety issues observed in the UNITY-CLL study posed to FDA approval. ¶ 133. That same day, Mr. Weiss stated in a conference call that the Company was "digging hard" into the OS data, explaining that, following the FDA's September

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[6] FDA Industry Guidance (December 2018).

[7] There is no allegation that the Company or any of the Individual Defendants learned that the FDA would request an ODAC meeting at any time prior to late November 2021. Moreover, there is no allegation that between the time that TG reported to FDA the OS data as of September 2021 through the time of this disclosure on November 30, 2021, the FDA made any conclusions about a causal link between the SAEs and U2 or UKONIQ, or required any changes to the UKONIQ label. Nor did it stop the ongoing clinical trials during this period. Indeed, as detailed below, the FDA did not withdraw its approval for UKONIQ until over six months later, after the submission of more recently-obtained data.

[8] FDA, Oncologic Drugs Advisory Committee (August 5, 2022), https://www.fda.gov/advisory-committees/human-drug-advisory-committees/oncologic-drugs-advisory-committee.

2021 request, the Company had "looked at the data in context ***and thought it was an early OS and was not problematic***" including when accounting for COVID-related deaths. The Company's interim analysis of OS data—based on the information available to it at the time—"showed an imbalance in favor of the control arm (HR: 1.23)[.]" ¶¶ 130, 178. However, ***when the Company excluded "deaths related to COVID-19, the two arms were approximately balanced (HR 1.04)***." 11/30/21 Press Release.[9] Moreover, based on the *ad hoc* nature of the analysis, approximately 15% of patients had missing or outdated survival data. ¶ 37. Mr. Weiss added, "And then obviously, ***there was a difference of opinion [by FDA], it's why they want to get this at the ODAC***[.]" ¶¶ 130, 178.

Nevertheless, the Company warned in the November 2021 announcement that several risk factors could impact its drug commercialization prospects, including "the risk [of] safety issues or trends observed in the UNITY-CLL study, including rates of serious adverse events and Grade 3 or greater adverse events" and "the risk that the outcome of the ODAC meeting is not favorable or, even if favorable, the FDA does not approve the U2 combination or does so in a narrowly defined population or imposes certain restrictions or warnings that negatively impact the commercial potential of U2 in CLL." ¶¶ 133, 176. Following the ODAC announcement, as part of its ongoing interim OS analysis, the Company sought to identify "missing" survival data for patients unaccounted for in the OS analysis generated based on the FDA's September 2021 request. ¶ 184.

Partial Clinical Hold on UNITY Trials. During the late 2021 timeframe, the FDA took no action to stop the UNITY-CLL trial, despite its awareness of the OS analysis discussed above. However, several months later, on January 27, 2022, the Company announced that the FDA had

[9] "HR" stands for Hazard Ratio, a metric which "measure[s] a patient taking a drug in a clinical study is more likely to die than a patient in the control arm," *i.e.*, a HR less than 1.00 indicates that a patient receiving the drug candidate is less likely to die than a patient in the control arm. ¶ 12 n.3.

imposed a partial clinical hold on the UNITY-CLL and UNITY-NHL trials. ¶ 136; 8-K (January 27, 2022) at 2. As a result of the partial clinical hold, no new patients could be enrolled in the CLL/NHL studies, but patients on these studies who were deriving clinical benefit were permitted to continue on therapy if they chose to do so. 8-K (January 27, 2022) at 2. At that time, TG noted that the partial clinical hold was not based on any new information provided by the Company to the FDA, but instead appeared to be based on the same data and concerns that gave rise to the previously announced ODAC meeting—*i.e.*, the FDA had simply come to a new conclusion based on data from months earlier.

Subsequent OS Analysis. From November 2021 to January 2022, the Company continued to analyze data related to the UNITY-CLL trial. ¶¶ 135, 180, 182, 184, 191. This included tracking down survival information for patients not previously accounted for in the original analysis prompted by the FDA's September 2021 request. ¶ 184. In a March 1, 2022 conference call, Mr. Weiss explained, "[Following the ODAC request] [w]e spent the next 2 months trying to close the information gap. We were pleased to report about a month ago that we're able to reduce the missing survival information from 15% down to 5%. And we were further pleased to report at a high level that … ***the overall survival hazard ratios improved from what we had seen in the original submission to the FDA.*** We provided that update to the FDA late last month." ¶ 139.

April 2022 Voluntary Withdrawal of U2 BLA and sNDA Submissions and Voluntary Withdrawal of UKONIQ. On April 15, 2022, seven days prior to the scheduled April 22, 2022 ODAC meeting date, the Company announced the withdrawal of its BLA and sNDA submissions to the FDA for U2 in CLL. ¶¶ 40, 142, 188. The press release announcing the voluntary withdrawal explained that, between September 2021 and February 2022, the Company had reanalyzed overall survival data and resubmitted updated data to the FDA:

> In February 2022, the Company submitted updated OS data with the same September 2021 cut-off date, but with reduced missing data and additional OS events, ***which showed an improvement from the previously reported OS data.*** Neither the original preliminary OS results nor the updated preliminary OS results were statistically significant.

4/15/22 Press Release. However, as of two months later, in April 2022, "***recently updated*** overall survival (OS) data from the UNITY-CLL Phase 3 trial … showed an increasing imbalance in OS[.]" *Id.* Thus, the Company announced that it had voluntarily withdrawn the BLA and sNDA for U2 in CLL. *Id.* In the press release, Mr. Weiss stated that the Company was "very disappointed to see that the ***recently updated*** overall survival data showed an increasing survival imbalance in favor of the control arm." In addition, the Company announced that it had voluntarily withdrawn UKONIQ from sale for the approved indications for MZL and FL "primarily based on the withdrawal of the BLA and sNDA for U2 in CLL." The Company further warned that "based on the Company's decision to withdraw UKONIQ from sale, we anticipate that the FDA will withdraw the accelerated approval for the product." *Id.* During a conference call three days later, Mr. Weiss reiterated that updated data and "growing concerns" around the drug class had posed a risk to commercialization prospects. ¶ 191. He noted that the Company would continue to focus on ublituximab as a treatment for relapsing multiple sclerosis ("RMS"). 4/18/22 Special Call.

Extension of PDUFA Data for Ublituximab as a Treatment for RMS. Approximately six weeks later, on May 31, 2022, TG announced that the Prescription Drug User Fee Act ("PDUFA") date for ublituximab as a treatment for RMS was extended to December 28, 2022 to allow for review of new information that the Company had provided. ¶¶ 46, 149, 193.[10] There is no allegation that the Company or any Individual Defendant learned that the FDA would extend this PDUFA date at any time prior to May 2022.

[10] A "PDUFA" date is the date by which the FDA is expected to provide a response to an NDA or BLA submission. *See Fort Worth Emps.' Ret. Fund v. Biovail Corp*, 615 F. Supp. 2d 218, 222 (S.D.N.Y. 2009).

Withdrawal of FDA Approval for UKONIQ. In June 2022, six weeks after TG had already voluntarily withdrawn UKONIQ from the market and warned that the FDA would likely withdraw its approval as a result (4/15/22 Press Release), the FDA officially withdrew the approval of UKONIQ for MZL and FL, citing more recently-updated findings from the UNITY-CLL clinical trial. ¶¶ 48, 152, 195; 6/7/22 Press Release.

TG Therapeutics' AE Reporting to the FDA. Under applicable regulations, drug candidate sponsors must report certain categories of adverse events ("AEs") to the FDA on a specified timetable. The Amended Complaint draws from publicly available data in order to compile AEs reported by TG Therapeutics, totaling 150 AEs—of these, 66 are "SAEs" and 19 resulted in death. ¶¶ 13, 98; AC Ex. 2. Notably, the supposedly "alarming" narrative of AE reporting in the Amended Complaint does not contextualize these SAEs in any way, including to account for the fact that the time period when the Company was supposedly experiencing an "alarming" (¶¶ 19, 29, 35, etc.) uptick in deaths of seriously ill patients who were immunocompromised coincided with the COVID-19 pandemic.[11]

ARGUMENT

In order to state a claim under Section 10(b) of the Exchange Act and Rule 10b-5 thereunder, Plaintiffs must plead, among other things: (1) particularized facts explaining how and why any relevant disclosures supposedly constituted a material misrepresentation or were misleading due to omission of a material fact; and (2) particularized facts giving rise to a strong inference of scienter with respect to each alleged misstatement or omission that is "cogent and at

[11] As the Company disclosed at the start of the Class Period, during this time, the COVID-19 pandemic had created a slew of risks related to biopharmaceutical clinical trials specifically, including the "an increased number of observed adverse events, as a result of participants enrolled in our clinical trials contracting COVID-19." 10-K (March 1, 2021) at 74.

least as compelling as any opposing inference of nonfraudulent intent."[12] Because Plaintiffs have failed to do so, dismissal is required.

I. PLAINTIFFS HAVE FAILED TO ALLEGE ANY ACTIONABLE STATEMENT OR OMISSION

Dismissal is required because to plead an actionable misstatement or omission, Plaintiffs must do much more than copy and paste TG's disclosures and declare that they were supposedly false and misleading. Instead, they "must demonstrate with specificity why and how that is so." *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F. 3d 227, 236 (2d Cir. 2014); *see also Novak*, 216 F.3d at 306.

A. The Amended Complaint Does Not Plead Any Actionable Misstatement

1. Plaintiffs Do Not Plead Facts To Challenge Defendants' Opinions That UKONIQ Was a "Differentiated Product"

The overwhelming majority of Plaintiffs' attempts to plead a false statement focus on disclosures that TG executives "thought" or "believed" that UKONIQ was a "differentiated product" in terms of its "safety profile" as compared to other PI3K inhibitors. *See* ¶¶ 19, 23, 29, 35, 106-7, 110, 115, 120, 129, 161-62, 167, 171, 174-75, 184, 191, 219. These are statements of opinion. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 183-84 (2015) (phrases such as "I think" or "I believe" often serve as indicators that the statement is one of opinion). Under Second Circuit law, to adequately plead a securities claim on the basis of a statement of opinion, a plaintiff must plead facts to demonstrate that (i) the speaker did not subjectively believe the opinion; (ii) the opinion contained one or more embedded factual statements that was false; or (iii) the statement failed to provide "critical context," meaning that

[12] *ECA, Loc. 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 197-98 (2d Cir. 2009); *Novak v. Kasaks*, 216 F.3d 300, 306 (2d Cir. 2000); *see also Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 314 (2007); 15 U.S.C. § 78u-4(b)(2); Fed. R. Civ. P. 9(b).

the speaker implied he or she had a reasonable basis for the opinion but in fact did not. *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 175 (2d Cir. 2020) (citing *Omnicare*, 575 U.S. at 188). Plaintiffs do not come close to satisfying these pleading thresholds.

First, there are no facts pled at all to suggest that any of the Individual Defendants did not subjectively believe that UKONIQ was a "differentiated product" in terms of its "safety profile" as compared to other PI3K inhibitors. *Second*, to the extent that the statements can be said to "embed facts" regarding a comparison of UKONIQ's safety profile to that of other PI3K inhibitors, nowhere in the Amended Complaint is any purportedly embedded "fact" alleged to be false. *See, e.g.*, *Arkansas Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 355 (2d Cir. 2022) (determining statements were not actionable where the plaintiffs "make no claim (and allege no facts indicating) that these statements of opinion were false"). By their terms, these opinions discussed a *comparison*—between TG's UKONIQ product and other PI3K inhibitors. But there is not a single allegation concerning the safety profiles of *any* other product so as to suggest that UKONIQ's safety profile was not "differentiated"—whether because of alleged SAEs or any other factor.[13] This failure alone defeats Plaintiffs' claims of falsity with regard to these opinion statements. *See Bristol-Myers Squibb Co.*, 28 F.4th at 355 ("Although the Investors argue at length that the trial was riskier than the Investors (with hindsight) believe was necessary, they make no claim (and allege no facts indicating) that [the challenged] statements of opinion were false.").[14]

Third, Plaintiffs do not plead that the Company's statements of opinion relating to differentiation "lacked critical context," *i.e.*, that the Company suggested there was a reasonable

[13] This is so notwithstanding that Plaintiffs had access to SAE data for other PI3K inhibitors through the FDA. *See infra* at Section I.B.1.

[14] Similarly, while Plaintiffs cite Mr. Weiss's statement in September 2021 that data from an "integrated safety analysis of 371 patients treated with UKONIQ," which was published in *Blood Advances*, "further support the differentiated safety profile of UKONIQ" (¶ 120), they allege no facts whatsoever to suggest this analysis somehow did *not* support the differentiated safety profile of UKONIQ.

basis for the opinion when there was none. *Abramson*, 965 F.3d at 175 (citing *Omnicare*, 575 U.S. at 188); *Omnicare*, 575 U.S. at 189. The example set forth in *Omnicare*, and reiterated by the Second Circuit in *Abramson*, is instructive. In *Omnicare*, the Supreme Court explained that the statement, "We believe our conduct is lawful," implies critical context, *i.e.*, "that a lawyer was consulted, since a reasonable investigation on this point would require consulting a lawyer." *Omnicare*, 575 U.S. at 199. Had the company not, in fact, consulted with a lawyer, the statement as phrased would be omitting this "critical context" and would be misleading on this basis. *Id.* There are no such facts alleged here. Plaintiffs do not allege that the Company's statements of opinion about the comparative safety profile between UKONIQ and competitor products were *not* based on clinical trial data or other reasonable sources, as would be required to state a claim on the basis of missing "critical context." *Abramson*, 965 F.3d at 175; *Omnicare*, 575 U.S. at 189.

2. Statements Regarding FDA Prospects Are Safe Harbored

Many of the statements challenged by Plaintiffs are prototypical forward-looking statements and are thus protected by the PSLRA's statutory safe harbor. 15 U.S.C. § 78u–5(c)(1)(A)(i). The safe harbor protects speakers from liability for making forward-looking statements where those statements are "identified and accompanied by meaningful cautionary statements." *Id.* Alternatively, because the safe harbor is written in the disjunctive, where a forward-looking statement is deemed "immaterial," *or* where the plaintiff "fails to prove that it was made with actual knowledge that it was false or misleading," the speaker is similarly not liable. *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 766 (2d Cir. 2010). As multiple of these conditions apply, the Company's forward-looking statements here are not actionable.

As a threshold matter, a number of the statements challenged by Plaintiffs qualify as forward-looking statements. The Amended Complaint identifies a number of statements relating

to the expectation of the completion of FDA submissions, FDA approval, and/or subsequent commercialization of UKONIQ and/or U2—including statements related to the projected timelines associated with these benchmarks. *See, e.g.*, ¶¶ 163 ("With the UKONIQ launch underway, we are excited to keep the momentum going and expect this year to complete our BLA submission for U2 in CLL . . ."), 169 ("We believe this solid commercialization foundation will support, if approved, the launch of U2 in CLL."); 171 ("[W]e strive toward obtaining FDA approval of the investigational combination of UKONIQ and ublituximab."). However, it is well-settled that "[p]rojections about the likelihood of FDA approval are forward-looking statements," and that statements about the approval process itself are "classically forward-looking." *Schaeffer v. Nabriva Therapeutics plc*, No. 19 CIV. 4183 (VM), 2020 WL 7701463, at *10 (S.D.N.Y. Apr. 28, 2020) (citing, *inter alia*, *Gillis v. QRX Pharm. Ltd.*, 197 F. Supp. 3d 557, 585 (S.D.N.Y. 2016)). As a matter of law, none of these statements is actionable.

The "meaningful cautionary language" that properly accompanied the Company's forward-looking statements relating to the FDA approval process and potential commercialization wholly precludes liability. By way of example, the Company concluded its March 2, 2021 press release stating its expectation of submitting of the U2-CLL BLA by year-end by cautioning that statements made therein were "subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied" in the release. 3/2/21 Press Release. The Company specifically identified its "ability to complete regulatory submissions within the timelines projected, including *completion of the rolling BLA submission* for ublituximab in combination with umbralisib in CLL," as a risk factor that could impact its ability to achieve projected results. *Id.* The release also explicitly identified "***the risk that the interim, top-line and preliminary data from our clinical trials that we announce or***

publish may change, or the perceived product profile may be impacted, as more patient data or additional endpoints (including efficacy and safety) are analyzed," and the risk that "actions of regulatory agencies. . . may affect the initiation, timing and progress of clinical trials." *Id.* (emphases added). The Company's cautionary statement issued in August 2021 was similarly thorough and included the same warnings. 8/2/21 Press Release. This careful and thorough articulation of risks and potential adverse outcomes easily satisfies the PSLRA's requirement that statutorily-protected forward-looking statements be accompanied by "meaningful cautionary language." 15 U.S.C. § 78u–5(c)(1)(A)(i). In any event, none of these statements is alleged to have been false or misleading—Plaintiffs merely allege that there were SAEs observed, which, as explained below in Section I.B., is entirely insufficient to allege a material misstatement.

Finally, the forward-looking statements are separately protected by the PLSRA statutory safe harbor because Plaintiffs have failed to plead that the statements were made with "actual knowledge that they were false or misleading." *Schaeffer*, 2020 WL 7701463, at *10. While the Amended Complaint fails to plead an inference of recklessness (let alone a strong one), *see infra* Section II, "forward-looking statements are held to an [even] higher pleading standard." *Id.* Here, as in *Schaeffer*, the Amended Complaint "simply does not allege that Defendants *actually knew* their statements about [the product's] likelihood of approval or their intentions to launch [the product] shortly after approval were false and misleading when made." *Id.* Similarly, therefore, the Company's forward-looking statements here are plainly protected by the PSLRA's safe harbor "for this reason alone", *id.*, further requiring dismissal.

3. Plaintiffs Do Not Plead Any Other Actionable Statements

By copying and pasting wholesale from TG's disclosures into the Amended Complaint, Plaintiffs purport to challenge numerous statements by TG that make no reference to any TG product's safety profile whatsoever, and that are not alleged to otherwise be actionable. For

example, an excerpt of the March 2, 2021 earnings conference Plaintiffs cite (from months before the alleged "uptick" in SAEs began) merely references the Company's delivery of results from the UNITY-NHL and UNTIY-CLL studies, as well as a statement about the projected timeline for the U2-CLL BLA submission. ¶ 163.

Like all of the statements Plaintiffs cite, these statements are not actionable: the first statement is a recitation of the steps taken by the Company to deliver its clinical trial results which is not alleged to be false, and the second statement is precisely the type of expression of "corporate optimism" that is routinely held to be inactionable. *See, e.g.*, *In re EDAP TMS S.A. Sec. Litig.*, No. 14-cv-6069-LGS, 2015 WL 5326166, at *9-10 (S.D.N.Y. Sept. 14, 2015) (statements that FDA process was "on track," making continued "progress," and that the Company believed it was "moving through the approval process in a timely manner" were all inactionable statements of corporate optimism); *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 757 (S.D.N.Y. 2018) (assertions of a company's "remarkable progress" in "advancing [its] expanding pipeline toward commercialization" constituted puffery).[15]

B. The Amended Complaint Does Not Plead Any Actionable Omissions

In recognition that TG made no misstatements, Plaintiffs' core allegation is that TG omitted information. That theory fails, because, "for an omission to be considered actionable under § 10(b), the defendant must be subject to an underlying duty to disclose." *Levitt v. J.P. Morgan Sec., Inc.*, 710 F.3d 454, 465 (2d Cir. 2013); *see also Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). Plaintiffs identify no omitted information that TG had a duty to disclose.

[15] *See also, e.g.*, 8/2/21 Press Release ("We are pleased with the progress made throughout the second quarter."); January 10, 2022 40th Annual Healthcare Conference hosted by J.P. Morgan ("Like I said, everything we've done thus far gives us a high level of confidence that the drug is not unduly unsafe. And so we're working toward that. So that hopefully would follow a favorable outcome…").

1. TG Had No Duty To Disclose SAEs

The crux of the Amended Complaint is that TG should have disclosed the existence of alleged SAEs. But as the U.S. Supreme Court has held, the securities laws do not impart a *per se* duty on pharmaceutical companies to disclose adverse events—including because "[a]dverse event reports are daily events in the pharmaceutical industry[.]" *Matrixx*, 563 U.S. at 43. Consequently, the "mere existence of reports of adverse events" will not give rise to securities liability. *Id.* at 44.[16] Rather, "[s]omething more"—including, critically, the "context" of the reports—is needed. *Id.* Here, there is nothing more.

Causation Requirement. As the Supreme Court recognized in *Matrixx*, "the mere existence of reports of adverse events . . . says nothing in and of itself about whether the drug is causing the adverse events[.]" *Id.*; *see also Rice as Tr. of Richard E. & Melinda Rice Revocable Fam. Tr. 5/9/90 v. Intercept Pharms., Inc.*, No. 21-CV-0036 (LJL), 2022 WL 837114, at *8 (S.D.N.Y. Mar. 21, 2022) (same). Thus, to plead that Defendants had a duty to disclose SAEs, the "something more" they must plead includes facts to suggest that the SAEs were casually connected to the Company's drug *at the time Plaintiffs allege they should have been disclosed*. But here, the SAE reports on which Plaintiffs themselves rely belie that suggestion, as they include the following Disclaimer:

> Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. ***The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship*** and cannot be used to estimate the incidence of these events.

[16] As the Supreme Court held in *Matrixx*, one of the key underpinnings of the disclosure laws is to prevent investors from being flooded with unnecessary, incomplete, and out-of-context information. *Matrixx*, 563 U.S. at 38.

AC Ex. 2 at 1. These reports also fatally undermine Plaintiffs' unsupported allegation that "in November [2021], TG reported to the FDA that UKONIQ *caused* thirteen more SAEs" (¶ 122); as cases like *Matrixx* recognize, reporting an SAE does not establish the SAE's cause. *See also* ¶¶ 31, 172.

Conflation. In fact, the Amended Complaint fails to even distinguish *which* therapy the SAEs it alleges were supposedly attributable to, *i.e.*, whether the alleged SAEs were observed in a patient receiving U2, UKONIQ, ublituximab, another TG drug candidate, or a control drug manufactured by another company altogether. Tellingly, Plaintiffs describe an alleged failure to disclose "the increase in [SAEs] the Company was seeing and reporting to the FDA related to UKONIQ" by the commencement of the Class Period, and then specify "four new SAEs" reported in the prior six months resulting in hospitalization or "other serious important medical event[s]." ¶ 105. But as illustrative of this "sharp uptick," (*id.*), Plaintiffs attach an exhibit identifying these specified SAEs—all four of which relate to patients treated with ***obinutuzumab***, ***a competitor drug*** to UKONIQ and U2. *See* AC Ex. 2 at 8-11 (listing SAE reports as received by the FDA on August 6, 2020, September 30, 2020, December 1, 2020, and December 6, 2020).

Patient Population. In conclusorily labelling a purported increase in SAEs as "alarming," Plaintiffs fail to account for a critical variable: SAEs, including deaths, would be *expected* given that TG's products were "designed to treat people that are already ill." *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 41 (2d Cir. 2000). Nor do Plaintiffs otherwise contextualize the data in any way, including with respect to trial population sizes, some of which numbered in the hundreds, or account for the fact that the alleged "uptick" in SAEs coincided with the COVID-19 pandemic.

Control Arm Comparison. While Plaintiffs heavily emphasize allegations concerning SAEs that they suggest (without particularized factual allegations) were attributable to TG

therapies, they plead no comparative data about SAEs in the "control" arm of the study so as to "plausibly indicate[] a reliable casual link between [the drug] and [the SAEs]." *Matrixx*, 563 U.S. at 45; *see also In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 214 (S.D.N.Y. 2008) (dismissing claim because the plaintiffs failed to "allege facts that, if proven, would support an inference that a causal relationship between [the drug] and [the AEs] was established but not disclosed during the Class Period").

Data Was Publicly Available. Finally, Plaintiffs entirely ignore that the SAE data they assert should have been disclosed was publicly available—a fact which, standing alone, defeats their claims. Since purported omissions are not actionable absent a duty to disclose the information, "[w]here allegedly undisclosed material information is in fact readily accessible in the public domain . . . a defendant may not be held liable for failing to disclose this information." *In re Bank of Am. AIG Disclosure Sec. Litig.*, 980 F. Supp. 2d 564, 576 (S.D.N.Y. 2013); *In re KeySpan Corp. Sec. Litig.*, 383 F. Supp. 2d 358, 377 (E.D.N.Y. 2003). Here, the Complaint "makes clear [that] the SAEs it identifies come from the FDA's FAERS database . . . [which] is publicly available."[17] Likewise, Plaintiffs concede they were able to obtain this data from the FDA in preparing the Amended Complaint. ¶ 98. And although Lead Plaintiff in this action is a sophisticated investor, the public accessibility of the SAEs would preclude claims as to *all* plaintiffs in this action regardless of their sophistication. *See Rice*, 2022 WL 837114, at *10 ("Regardless of Plaintiff's sophistication to navigate the FAERS data, the FAERS data is public information and an efficient market incorporates 'all publicly available information.'" (quoting *In re Acadia Pharms. Inc. Sec. Litig.*, No. 18-cv-01647-AJB-BGS (S.D. Cal. Mar. 29, 2021), ECF No. 101)). Accordingly, while

[17] *Rice*, 2022 WL 837114, at *10; s*ee also* AC Ex. 2 (including SAE data similarly available on the FDA Adverse Reporting System); FAERS Data.

TG had no duty to disclose SAEs for the reasons set forth above, in any event, that data was already available to, and incorporated in, the market.

2. TG Had No Duty To Disclose The FDA's September 2021 Information Request

Plaintiffs further assert that TG's statements from August and September 2021 were supposedly false or misleading because the Company had "received a request from the FDA for an overall survival analysis, which the Company knew but failed to disclose." ¶ 172.

As an initial matter, as to the August 2021 disclosure, Plaintiffs' allegation is illogical, given that they plead that TG received the FDA information request "in *September* 2021," ¶ 27; TG therefore could not have had any duty to disclose that request a month earlier, in August.

In any event, TG had no duty to disclose the FDA's information request once it was received. Rather, "[n]umerous courts across the country have found that defendants in securities fraud actions had no obligation to disclose the substance of FDA inquiries made during the pendency of a drug or device application." *EDAP*, 2015 WL 5326166, at *29; *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 534 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016) ("The law did not impose an affirmative duty to disclose the FDA's interim feedback just because it would be of interest to investors." (citing *Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002))). And while Plaintiffs allege in a conclusory fashion that the FDA's request for information "call[ed] the drugs' approval into question" (¶ 121), they plead no facts to support that conclusion. Indeed, courts have long recognized that interim requests for information by the FDA are routine in the drug development process and do not by themselves give rise to any disclosure obligation. *See In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) ("Mere questioning by the FDA imposed no duty upon Defendants either to trim back their opinions as to the efficacy of the drug or to report to the public the FDA staffers' questions as they

arose. . . . Defendants, as a general proposition, had no duty to report its [sic] ongoing discussions with FDA during the review process."). That is especially so because at no point did TG guarantee the eventual approval by the FDA for any of its products. *See In re Alkermes Sec. Litig.*, No. 03–12091, 2005 WL 2848341, at *16 (D. Mass. Oct.6, 2005) ("Defendants had no duty to disclose that the FDA had requested additional studies because they [] never guaranteed FDA approval.").[18]

C. Plaintiffs' Allegations As To Disclosures Beginning In November 2021 Merely Allege "Fraud by Hindsight"

While Plaintiffs purport to challenge disclosures by the Company from November 2021 through May 2022 for supposedly failing to disclose that TG's chances of obtaining approval for U2 were in "jeopardy" and because they allege that the "risk[s] to U2's BLA/sNDA approval as well as the withdrawal of approval for UKONIQ were already transpiring," (¶¶ 172, 177), this illogical set of allegations relies impermissibly on the theory of fraud by hindsight: Plaintiffs aver that subsequent actions by the FDA rendered false any previous statements by the Company that did not presage those events. That is not "fraud." *See In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 267 (2d Cir. 1993) (statements that are not alleged to be "false when the statements were made" are non-actionable); *In re Pfizer Inc. Sec. Litig*, 538 F. Supp. 2d 621, 634 (S.D.N.Y 2008) (drug's "ultimate failure is not evidence that the side effects were thought to be unmanageable at the time the alleged misstatements were made"); *see also Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000) ("Corporate officials need not be clairvoyant. . . . [A]llegations that defendants should have anticipated future events and made certain disclosures earlier than they actually did do not suffice to make out a claim of securities fraud.").

[18] In fact, far from "guaranteeing" FDA approval, Mr. Weiss noted in the September 2021 press release that "***As we strive toward*** obtaining FDA approval of the investigational combination of UKONIQ and ublituximab, U2, in CLL by the PDUFA goal date of March 25, 2022, ***furthering our understanding of the safety and tolerability profile of UKONIQ remains paramount to us***." 9/23/21 Press Release.

Specifically, Plaintiffs allege that the Company's disclosures beginning in November 2021 and continuing through the end of the Class Period "significantly downplayed the impact that the increasing SAEs and deaths would have on the FDA's assessment of the safety of UKONIQ."[19] ¶¶ 38, 141. But there is nothing to suggest that any of the Company's statements was false or misleading when made. Rather, as the Amended Complaint reflects, at the time, analysis of survival data remained *ongoing*. ¶¶ 27, 117. Disputes about the interpretation of data do not constitute securities fraud. *See Tongue*, 816 F.3d at 214; *Kleinman v. Elan Corp.*, 706 F.3d 145, 154 (2d Cir. 2013); *Gillis*, 197 F. Supp. 3d at 599. Moreover, courts recognize that corporations are entitled to reasonable time to evaluate such data. *See Elan*, 543 F. Supp. 2d at 217 ("[a] more reasonable inference is that Defendants used this time to investigate, to gather more information, and to confer with . . . the FDA before taking any action").

In this regard, the Amended Complaint mischaracterizes how the Company's OS data analysis, in fact, proceeded leading up to TG's voluntary withdrawal on April 15, 2022—by that point, the Company had submitted *updated* OS data in February 2022 that "*showed an improvement from the previously reported OS data*." 4/15/22 Press Release. Only following a *subsequent* FDA information request did the Company conduct additional OS analysis as of April 2022 that showed "an increasing imbalance in favor of the control arm, differing from the improved results provided to the FDA in February 2022." *Id.*[20] With this new OS data in hand,

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[19] Plaintiffs also allege that TG's stock price remained artificially inflated following the November 30, 2021 press release because TG supposedly created a false impression that FDA approval was "still assured." ¶ 212. But nothing in the Company's statements gave any "assurance" of FDA approval; to the contrary, TG warned that FDA approval could be imperiled. 11/30/21 Press Release. Of course, Plaintiffs cannot premise a claim on statements of their own invention. *See In re Stemline Therapeutics Inc. Sec. Litig.*, 313 F.Supp.3d 543 (dismissing "Section 10(b) claim … that Stemline falsely claimed it had eliminated the risk of [a side effect] because "it is clear that Stemline never claimed that it had eliminated [those] risks; 'elimination' is a fabrication by Plaintiffs.").

[20] In fact, Plaintiffs' own allegations illustrate the real-time efforts the Company was making to investigate the FDA's inquiries regarding overall survival as it learned of those inquiries contemporaneously. For example, as to statements made during the Company's November 30, 2021 conference call, Plaintiffs assert, without basis, that the FDA had "revealed" that the Company's "clinical trial results. . . were misrepresented." ¶ 178. In fact, the comments

the Company made the decision in April 2022 to withdraw its U2 applications with the FDA, which it promptly disclosed. The fact that the Company did not accurately predict these events before they transpired is not "fraud."

II. PLAINTIFFS FAIL TO ALLEGE FACTS SUPPORTING A STRONG INFERENCE OF SCIENTER

Even assuming, *arguendo*, that Plaintiffs have alleged an actionable misrepresentation or omission (they have not), Plaintiffs' claims would still fail as a matter of law because the Amended Complaint fails to allege *any* facts to plead scienter, let alone the required *particularized* facts demonstrating a *strong inference* of scienter with respect to each act or omission that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 314 (2007); 15 U.S.C. § 78u-4(b)(2). Under Second Circuit law, to adequately allege scienter, Plaintiffs must plead with particularity facts giving rise to the required strong inference that either (i) show that each Defendant had the motive and opportunity to commit fraud; or (ii) constitute strong circumstantial evidence of conscious misbehavior or recklessness. *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 483 F.3d 87, 105 (2d Cir. 2007). On both prongs, the Amended Complaint fails.

A. Plaintiffs Do Not Allege Any Plausible Motive to Commit Fraud

Plaintiffs have not pled motive to commit securities fraud, because the Amended Complaint alleges not a single "concrete and personal benefit" from the alleged (non-existent) misrepresentations or omissions. *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001).

Plaintiffs quote make clear that Mr. Weiss was reporting the Company's *interpretation* of the initial overall survival data requested by the FDA, and the basis for the FDA's follow-up request for an ODAC meeting. ¶ 178 ("[W]e're now digging in hard to the [overall survival] data. Again, we looked at the data in context and thought it was an early OS and was not problematic. And then obviously, there was a difference of opinion on that, it's why they want to get this at the ODAC."). That is not a basis to assert a 10(b) claim. *See Gillis*, 197 F. Supp. 3d at 598 (as to an interpretive question upon "reasonable minds could differ. . . [t]hat the FDA. . . ultimately disagreed with defendants' interpretation of the data does not render their subjective assessments false or misleading").

The only particularized motive allegation in the Amended Complaint is that the compensation structures for Defendants Weiss and Power included annual cash incentives for meeting certain *regulatory* achievements, *i.e.*, that they could earn additional incentive compensation if the Company achieved certain milestones with FDA approval. ¶ 237.[21] But to plead motive, Plaintiffs must allege that Defendants were incentivized to commit securities fraud, *i.e.*, "to inflate stock prices." *Kalnit*, 264 F.3d at 139. Plaintiffs do not allege that Defendants Weiss and Power were motivated to inflate stock prices, only that they were motivated to achieve FDA approval, file the U2 BLA and sNDA, and meet "[v]arious goals associated with the commercial launch for UKONIQ." ¶ 237. Nothing about the alleged "fraud" would have helped them with those goals—while Plaintiffs conclusorily allege that "Defendants were motivated to mislead . . . the FDA for the purposes of achieving those goals," (*id.*), there is not a single fact alleged to suggest that TG misled the FDA in any way. To the contrary, the core allegation Plaintiffs advance—that there were SAEs—is based in significant part on the Company's own contemporaneous reporting to FDA.[22]

In any event, even if Plaintiffs' motive allegations made any sense (they do not), they would still be insufficient, because "the Second Circuit's case law . . . clearly provides that an incentive-based compensation system is generally insufficient to support a strong inference of scienter." *In re Skechers USA, Inc. Sec. Litig.*, 444 F. Supp. 3d 498, 526 (S.D.N.Y. 2020); *Kalnit*, 264 F.3d at 140 ("[A]n allegation that defendants were motivated by a desire to maintain or increase executive compensation is insufficient because such a desire can be imputed to all corporate officers."). Rather, it is well-established that motive allegations are not satisfied by

[21] Plaintiffs make no attempt at all to plead any motive by the other Individual Defendant, Mr. Waldman.

[22] To the extent that Plaintiffs allege Mr. Weiss and Mr. Power were motivated to file the BLA and sNDA for U2, there is nothing to connect that alleged desire to the supposed "fraud." In fact, TG submitted the U2 BLA on March 25, 2021 and the U2 sNDA on May 25, 2021—months before the alleged "severe uptick" of SAEs. ¶ 115.

incentives shared by "virtually all corporate insiders" such as "the desire to maintain a high stock price in order to increase executive compensation." *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009); *see also In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 560-61 (S.D.N.Y. 2004) ("[I]f performance-based compensation were a sufficient predicate for fraud, then 'virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions.'" (quoting *Acito v. IMCERA Grp, Inc.*, 47 F.3d 47, 54 (2d Cir. 1995))); *Gillis*, 197 F. Supp. 3d at 600 ("As to motive, the [complaint] does not allege that defendants had a motive to defraud the public. And the facts pled do not reveal any incentive to inflate QRX's stock price by pretending, during the period of FDA review, that approval of MoxDuo was likely when (as plaintiffs posit) defendants knew the Superiority Requirement foreclosed approval . . . .").

B. Plaintiffs Do Not Sufficiently Allege Conscious Misbehavior or Recklessness

Plaintiffs also fail to plead any inference of conscious misbehavior or recklessness. ¶¶ 154-191, 232-235, 238-245. To state a claim under a recklessness theory based on a material omission, as Plaintiffs seek to do here, they must allege that the Defendants had "knowledge of facts or access to information contradicting their public statements," and plead particularized facts supporting a strong inference of Defendants' "conscious recklessness." *Novak*, 216 F.3d at 312. In addition, where, as here, no motive is alleged, the circumstantial evidence of conscious misbehavior 'must be greater' and show 'highly unreasonable' behavior or that which evinces 'an extreme departure from the standards of ordinary care.'" *Rice*, 2022 WL 837114, at *21 (quoting *Kalnit*, 264 F.3d at 142); *see also Novak*, 216 F.3d at 308 (to allege recklessness, Plaintiffs must allege conduct which "represents 'an extreme departure from the standards of ordinary care'" and is so severe that it "approximat[es] actual intent, and not merely a heightened form of negligence"). The Amended Complaint fails to satisfy this high standard.

Plaintiffs' conclusion that Defendants supposedly "knew, or were reckless in not knowing, that poor results or low survival rates in the UNITY-CLL trial would almost certainly result in the FDA refusing to accept the Company's expedited application" (¶ 235; *see also* ¶¶ 18, 25, 42, 104-141, 154-187) is not supported by a single well-pled factual allegation. In fact, Plaintiffs' allegations attributed to so-called "confidential witnesses" actually confirm the *lack* of fraudulent intent by TG, rather than give rise to a strong inference of such intent. In order to support an allegation of scienter based on confidential witnesses, plaintiffs "must describe the nature of the of the CW's contact with the individual defendants *that would be probative of defendants' [allegedly fraudulent] mental state*." *Maloney v. Ollie's Bargain Outlet Holdings, Inc.*, 518 F. Supp. 3d 772, 780 (S.D.N.Y. 2021). Notably, during the September 30, 2022 Lead Plaintiff hearing, Plaintiffs' counsel represented to the Court that they had contacted more than *two hundred* purported confidential witnesses in an effort to bolster the allegations in the Amended Complaint. Transcript of Lead Plaintiff Hearing at 40. But confirming the lack of any fraud, the Amended Complaint cites only four such purported witnesses. Of those, none of CW1, CW2, or CW3 are alleged to have had *any* contact with any of the Individual Defendants. And most critically, none of the supposed confidential witnesses purports to describe *any* fraudulent intent.

Indeed, as to CW4, Plaintiffs only allege that this confidential witness attended a "mandatory company-wide Zoom call" in "approximately September 2021" on which Mr. Weiss supposedly "addressed a 'pocket of SAEs (Serious Adverse Events)' related to UKONIQ and again employees were provided the same rationale that the deaths were due to COVID rather than TG's drug." ¶¶ 28, 118. At most, this would suggest that Mr. Weiss was aware of certain SAEs at some unspecified time and believed they were attributable to COVID and not a new and "alarming"

change in the safety profile of the Company's drugs.[23] Indeed, in this regard, the complaint fails to plead scienter "much for the same reasons it fails to plead falsity." *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 765 (S.D.N.Y. 2018).[24] As explained at length above, the Amended Complaint lacks any supporting facts from which the Court could infer (let alone *strongly* infer) that knowledge of a "pocket" of SAEs (whatever that supposedly means) meant that the FDA would ultimately take the actions it did many months later or that it contradicted any of Mr. Weiss's statements. To the contrary, the Amended Complaint paints a picture in which TG continued to remain optimistic based on its own interpretation of the OS data, believing that many SAEs were attributable to COVID and that as "missing" data was reconciled, the numbers would continue to improve. *See supra* at p. 9-10.[25] Thus, CW4's allegations, if credited, would confirm the *lack* of any fraudulent intent by Mr. Weiss: if Mr. Weiss indeed made a statement attributing SAEs to COVID (the allegations are vague as to *who* supposedly made that statement, if anyone), it would support the conclusion that Mr. Weiss believed that SAEs the Company was seeing were attributable to COVID, rather than to any problems with the Company's products. As such, Plaintiffs' allegation concerning Mr. Weiss' statement does not demonstrate a strong inference of

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[23] In any event, the purported confidential witness' account should not be credited because it is vague as to when the statement supposedly described actually occurred, and therefore does not satisfy the standard by which reliability of confidential witness testimony is measured. *See Menora Mivtachim Ins. Ltd. v. Int'l Flavors & Fragrances Inc.*, No. 19-CV-7536 (NRB), 2021 WL 1199035, at *11 (S.D.N.Y. Mar. 30, 2021) (confidential witness statements not credited where "the information that they offer is itself insufficiently particular").

[24] Plaintiffs do not allege that Mr. Power or Mr. Waldman were aware of any SAEs. And as to Mr. Waldman, he is alleged to have made only two statements cited in the Amended Complaint, both concerning the "differentiation" of UKONIQ (which are not actionable for the reasons set forth *supra* at Section I.A.1). Those statements were allegedly made in February and May 2021—*prior* to the alleged "undeniable uptick in serious adverse events and patient deaths" which Plaintiffs allege occurred in the *summer* of 2021. ¶¶ 24-25.

[25] For similar reasons, Plaintiffs' attempt to invoke the "core operations" inference (¶¶ 233-235) also fails, because they do not identify any information contradicting TG's public statements that was so important it "must have" been known by top-level executives. *See Jackson v. Abernathy*, 960 F.3d 94, 99 (2d Cir. 2020). In fact, all they plead is that U2 and its constituent drugs were important products to TG. That is insufficient. *See id.* (finding that the plaintiffs' allegation that product was a "key product" and of "such core importance" to company insufficient to allege scienter). In any event, "there is considerable doubt whether the core operations doctrine survived enactment of the PSLRA, and many courts have held that it is no longer valid." *Cortina v. Anavex Life Scis. Corp.*, No. 15-CV-10162 (JMF), 2016 WL 7480415, at *7 (S.D.N.Y. Dec. 29, 2016).

scienter that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314; 15 U.S.C. § 78u-4(b)(2).[26]

Thus, there are no facts to support any inference (let alone a strong one) that the Defendants believed that the FDA was unlikely to approve U2 or was likely to withdraw its approval of UKONIQ based on the occurrence of SAEs.[27] *Tellabs*, 551 U.S. at 314; 15 U.S.C. § 78u-4(b)(2). And of course, a defendant's intention to "deceive, manipulate, or defraud," (*Tellabs*, 551 U.S. at 313), cannot be alleged by pleading that a defendant omitted information that he or she had no duty to disclose to investors—including the SAE data on which Plaintiffs premise their claims. *See Rice*, 2022 WL 837114, at *22 ("Failure to disclose facts that Defendants had no duty to disclose cannot support a strong inference of scienter.").

III. PLAINTIFFS FAIL TO ESTABLISH ANY CONTROL PERSON VIOLATION

Plaintiffs' Section 20(a) claim alleging control liability (¶¶ 258-264) should be dismissed because Plaintiffs fail to plead a primary violation of Section 10(b). *See Chapman v. Mueller Water Prods., Inc.*, 466 F. Supp. 3d 382, 414 (S.D.N.Y. 2020).

[26] Likewise, the allegations in the Amended Complaint that Plaintiffs attribute to their purported expert witness add nothing. While the expert opines on a supposedly "alarming" number of AEs in the UNITY-CLL trial (¶ 99) and supposes that "such data would have been alarming the FDA and raised red flags" (¶ 116), the allegations attributed to her do not contain any particularized facts that raise a strong inference that anyone at the Company knew or should have known that the prospects for its drug candidates would be impacted by these adverse events.

[27] Indeed, after the Company's November 30, 2021 announcement concerning the ODAC meeting, analysts agreed that while FDA approval of the U2 applications was uncertain, it was premature to conclude that such approval was foreclosed. ¶ 213 (quoting Jefferies analyst report) ("While we agree today's update creates uncertainty to all of above critical aspects, we see it is too early to make [a] conclusion for negative outcomes[.]").

CONCLUSION

For the reasons stated herein, the Amended Complaint should be dismissed with prejudice in its entirety.

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Respectfully submitted,

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